DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 17-970/S-048

AstraZeneca Pharmaceuticals LP
1800 Concord Pike
P.O. Box 8355
Wilmington, DE 19803-8355

Attention: E. Jane Valas, Ph.D.
Associate Director, Regulatory Affairs

Dear Dr. Valas:

Please refer to your supplemental new drug application dated December 11, 2000, received December 12, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Nolvadex® (tamoxifen citrate) Tablets.

We acknowledge receipt of your submissions dated March 21, 2001, June 7 and November 25, 2002, and April 24 and June 3, 2003, received March 23, 2001, June 7 and November 26, 2002, and April 25 and June 4, 2003, respectively.

This supplemental new drug application provides for a Medication Guide for Nolvadex® Tablets.

We completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the enclosed labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the Medication Guide) and should include the latest package insert. Please also include with the FPL revisions to the package insert to provide a reference to the Medication Guide in the **PRECAUTIONS** section, **Information for Patients** subsection.

Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 17-970/S-048." Approval of this submission by FDA is not required before the labeling is used.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Christy Cottrell, Consumer Safety Officer, at (301) 594-5761.

Sincerely,

{See appended electronic signature page}

Richard Pazdur, M.D.
Director
Division of Oncology Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Enclosure

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Richard Pazdur

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